

Cardiopulmonary Diagnostics

At The Cutting Edge Of Cardiopulmonary Diagnostics

By Massimiliano Granieri

Introduction

Italian company Cosmed has a reputation for laboratory-based medical device products which is founded on sound IP. The market is competitive, with a limited number of players, so reputation is critical to securing a leading role. Patents assure customers that products are innovative. They increase visibility and recognition, and justify premium prices. When co-operating with external partners, IP also makes everyone's boundaries clear from the start and prevents any confusion moving forward. Medical technology must comply with regulatory requirements in order to enter the market. This takes time, so Cosmed chooses to establish IP early to safeguard its investments.



Performance diagnostics with spiroergometry using Cosmed's wearable metabolic technology.

Founded in 1980, Cosmed has become a leader in the fields of industrial design, the development and manufacture of diagnostic equipment, and scientific research in the med-tech industry. With a business model based on direct and network sales, it has established subsidiaries in Germany, France, Switzerland, the U.S., China, and Australia, and has distributors in Russia, Brazil and Korea.

The company's wide range of products includes spirometers, portable systems for the analysis of respiratory function and nutrition, and systems for the execution of cardiopulmonary exercise testing for metabolism and body composition. They can be used in a variety of fields, including pulmonary sports medicine, cardiology, clinical nutrition, rehabilitation and occupational medicine and pedagogic physiology.

One of the innovations that Cosmed has launched

on the world market since 2005 is the FitMate series, a set of products for measuring resting metabolic rate, maximum oxygen consumption and spirometric parameters. Competitive pricing, ease of use and low maintenance requirements have allowed Cosmed to penetrate market sectors that were previously inaccessible, such as fitness and private dietetics.

In 2006, Cosmed updated its entire range of stationary laboratory testing products. It introduced innovative modifications for the analysis of pulmonary function (Quark PFT), cardiopulmonary exercise testing (CPET Quark) and the determination of resting energy expenditure (Quark RMR) and launched the plethysmograph cabin (QBOX). These improvements were brought about by applying innovative approaches to user-driven input while marrying ICT solutions with effective product design. The products combine hardware and firmware with interface control (a house-developed proprietary software suite called Omnia, which is encrypted for security and runs on Windows platforms).

Over the years, Cosmed has established strategic and business agreements with other companies and institutions, as both supplier and customer. These companies include Ergoline, Bosch, Adidas (Germany), U.S. Army, Apple Inc. (U.S.), Nihon Kohden (Japan), NORAV (Israel) and the University of Rome Tor Vergata (Italy). Cosmed products have also been used in high-profile settings such as the James Bond film Skyfall, and the White House.

Reputation-Backed IP

Intellectual property plays a crucial role for Cosmed. The company has adopted a comprehensive approach to making the best use of patents, together with trade marks, design rights and copyright, to cover individual

"In this market, you cannot claim to have cutting-edge products and then let your customers discover that you don't have any patents. You must have patents."

Paolo Brugnoli,
Head of R & D and
lead inventor,
Cosmed



Cosmed's K5— A Wearable Metabolic System



Cosmed's K5, a wearable metabolic system designed for measuring metabolic parameters both in the field and in the laboratory.

products. Cosmed's FitMate, for example, is protected by patents, registered as a trade mark, and uses copyright-protected software.

The worldwide market for metabolic devices has a limited number of players, which makes the competitive environment more intimate. Because of these conditions, reputation is of the essence and is boosted by a solid IP portfolio. Establishing a strong IP position is instrumental in growing the company's market share, keeping other companies at bay and maintaining the capacity to enforce patents against infringers if necessary. Cosmed has added to its portfolio by acquiring a small manufacturing company with an attractive set of products and patents.

Cosmed relies on its patent portfolio to build its reputation in the med-tech industry, where high-tech and IP are synonymous with reliability and quality. In doing so it assures users that its products are of a high standard and designed for a positive impact on human health and life. A strong IP portfolio also justifies premium pricing for pioneering technology. Cosmed's brand name, market visibility and recognition are bolstered by a comprehensive IP portfolio, including trademarks and design rights that cover high-tech, user-friendly products.

Dealing with Market Particularities

Before they can be put on the market, medical devices must comply with regulatory requirements for safety and compatibility and must acquire certification. They must be reliable and affordable, and easy to use, clean and store. It can take up to 10 years for a product in the med-tech field to go from concept to market. Obtaining intellectual property rights early on creates safer conditions for investing in design and testing. Patents offer protection from imitation until the product can eventually be sold.

Holistic IP Management

It is important to have strong, high-quality patents originating from sound IP management in which internal and external influences on the patent portfolio are under control.

To develop innovative devices, Cosmed co-operates with external experts and consulting firms specialising in healthcare product design. Here again, careful management of intellectual property is very important to avoid loss of control of its innovative efforts and to prevent dilution or confusion with a third party's knowledge and concepts. Co-operation is safer when IP ownership is clearly defined from the outset. Established IP creates "transactional security," which makes parties more comfortable sharing information and open to co-development efforts that do not impinge on the proprietary knowledge and expertise of partners.

Positive Side Effects

Owning IP gives Cosmed a competitive advantage in public procurement bids, since the uniqueness of products protected by patents is one of the criteria that public administration bodies in Europe can apply in their bidding procedures for the purchase of products directly from dedicated suppliers.

Under the optional "patent box" tax regime recently introduced in Italy, and which also exists in similar form in many other countries, Cosmed has applied to the tax authorities for a so-called ruling agreement, which would give the company an extended tax break based on the contribution that its IP portfolio makes to its revenues. Although the agreement is still being negotiated, it is expected that Cosmed's large and composite IP portfolio will result in significant benefits.

Last but not least, IP is instrumental in contributing to Cosmed's equity value. The company is family-owned and its financial position is rock-solid. While there are no plans to sell the company or go public, senior management is always looking to boost corporate value. The company's IP is a crucial component of its intangible assets, as it helps to increase the visibility of R&D investments for potential investors and financial analysis while reinforcing Cosmed's credit rating.

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Aerogen Vibronic®—Technology Profile



The K5 is the fourth generation of Cosmed's family of wearable metabolic systems developed and designed for the measurement of metabolic parameters such as oxygen production (VO₂), carbon dioxide production (VCO₂), ventilation, energy expenditure and heart rate. The K5 unit contains 3D motion sensors and GPS in order to combine metabolic analysis with speed, cadence, stride, steps and related parameters. It also includes the IntelliMET patented dual gas sampling system (EP2769673), which allows users to choose between two different breathing modes. The mixing chamber mode can be used to obtain average measurements of oxygen and carbon dioxide consumption within a number of breathing cycles and is suitable for use on athletes. The breath-by-breath mode can be used to carry out instantaneous measurements of consumption during each breathing cycle and is suitable for applications in the clinical field.

User-Centred Strategy that Reduce Risks

Filing for IP protection comes with risk. Drafting and validating patent applications at national level is expensive, especially if it is not yet clear whether the product will ever reach the market or have a satisfactory uptake. To reduce such risks, Cosmed goes about product development with a user-centred approach and bottom-up design that aims to address the needs and requirements of users while realising spearhead products. When looking at user applicability, the company searches competitors' patents, both as a source of information, to improve on existing designs, as well as to assess freedom to operate (FTO) and avoid infringing third-party patents.

Prior Art Searches

In-depth prior art searches must be conducted early in the creative process, before research begins, and then professionally verified once the patent application has been drafted.

Cosmed's traditional business model is based on device sales, so keeping alignment with the technology roadmap, products and patents, as well as other types of IP, has always been central to its IP strategy. Occasionally, patent applications are filed for elements such as disposable parts rather than for entirely new devices, which can offer a significant market in high-volume sales. In this case, intellectual property becomes instrumental in protecting post-sale markets that include the supply of spare parts and maintenance services.

IP Management that Works

Because of budgetary constraints and uncertainty in relation to new product development, Cosmed exercises caution and foresight in its patenting decisions, particularly when it comes to protection in multiple countries. It uses an external IP firm to check that inventions are properly disclosed, to draft and prosecute patents, and to interact with patent authorities worldwide. The firm was carefully selected for its excellence, since it is vital to have high-quality patents that can be enforced in court. Strategic decisions about IP are taken by Paolo Brugnoli, head of the R&D Department and lead inventor of all Cosmed's patents, who has a direct report to the CEO.

Looking at the entire value chain from R&D to market entry, Cosmed conducts a number of activities in-house, from FTO analyses to prior art searches. When a potential invention is identified, the company sends a report to its IP firm for an initial evaluation, after which Paolo Brugnoli makes the final decision on whether or not to file. The IP attorneys then draft an application, which is reviewed by Cosmed before being filed.

External IP Support

IP strategy cannot be outsourced, but external expertise and support is important for feedback and for implementing strategic choices.

There are no formal guidelines for IP management within Cosmed, since too much formalisation is perceived as a hindrance to creativity, but an informal internal procedure is in-place. Through exposure to certification and quality control procedures, the company has learned how to manage complex processes, while its operations have been successfully kept lean.

Patent Filing Strategy for the Future

In the past, Cosmed has filed patent applications in Italy to earn a priority date and then extended them to U.S. and EP levels, and on occasion to China and Japan. At European level, validation decisions are driven by budgetary considerations, and the more appealing markets are typically those where Cosmed has direct sales through subsidiaries, although the European market is turning out to extend into countries beyond those where the patents have been validated to date. Recently, at least where it is clear that a product could

Cosmed's Bod Pod Gold Standard



Cosmed's Bod Pod Gold Standard is a body composition (fat and fat-free mass) tracking system that uses whole body densitometry.

have a wider market penetration, Cosmed has used the EP as a priority filing, to save money and time. The Unitary Patent will present an opportunity to cover an even larger market at European level, at a reduced cost. The savings can then be parlayed into future patents, thus reinforcing Cosmed's portfolio.

Although its patent portfolio is not huge, Cosmed has some difficulty coping with its management and the associated costs, particularly at the validation level, when budget constraints become more demanding and costs increase as a result of translations, renewal fees, issuance fees, validation fees at national levels, and so on. The Unitary Patent is likely to make the decision-making process much easier. Moreover, a system that allows for savings and wider geographic coverage will reinforce Cosmed's position on the European market, where its patent protection is currently limited to five countries (Italy, Germany, United Kingdom, France, the Netherlands), while its products are sold all over Europe.

Patent Portfolio Management

Budget considerations are necessary. It is important to reduce costs without sacrificing quality when creating and maintaining a portfolio, as long as it reinforces the business case and the patent system allows for it.

Although Cosmed hopes to avoid litigation in the future, the prospect of a Unified Patent Court is appreciated, as past experience with enforcing patents has made management aware of the disruption litigation can introduce. Litigation in multiple countries could have had even more disastrous consequences. With

strong patents to enforce, the Unified Patent Court seems to be the best solution and will also be a deterrent for potential infringers.

When it comes to the future, Paolo Brugnoli, an electronic engineer by training, has no doubt that the Unitary Patent system will provide more benefits, such as reduced administrative steps, which are his responsibility. It is also expensive for the company since he, as a senior manager, has to facilitate strategic decisions, as well as handle the particulars of the patent administrative procedure. Of course, the company could reorganise internally and have someone else be responsible for patents, but the current set-up has the advantage of having the head of R&D directly involved in IP management and in close contact with the corporate CEO. ■

Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=3068838>

Company Profile

Cosmed S.R.L.

- Headquarters: Albano Laziale, Italy
- Year of establishment: 1980
- Staff: 120
- Turnover: EUR 17 million
- www.cosmed.com

Products/Services

Biomedical devices for the measurement of resting metabolic rate, maximum oxygen consumption and spirometric parameters. The products are a combination of hardware and firmware with interface control.

Market and Technical Area

Biomedical devices and software.

Customers

Hospital care, universities and research centres, nutrition clinics, sports teams.

Selected Awards

2013 Product of Outstanding Interest
(European Respiratory Society)

Patent Portfolio

Three patent families, e.g. EP2769673, EP0196396

Photos: Cosmed S. r. l.

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